

## ADMINISTRATIVE RULES

### Fiscal Estimate & Economic Impact Analysis

<b>1. Type of Estimate and Analysis</b> <input checked="" type="checkbox"/> Original <input type="checkbox"/> Updated <input type="checkbox"/> Corrected	<b>2. Date</b> November 12, 2020
<b>3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)</b> CSB 4	
<b>4. Subject</b> Relating to designating Gabapentin as a monitored drug having substantial potential for abuse.	
<b>5. Fund Sources Affected</b> <input type="checkbox"/> GPR <input type="checkbox"/> FED <input type="checkbox"/> PRO <input type="checkbox"/> PRS <input type="checkbox"/> SEG <input type="checkbox"/> SEG-S	<b>6. Chapter 20, Stats. Appropriations Affected</b>
<b>7. Fiscal Effect of Implementing the Rule</b> <input checked="" type="checkbox"/> No Fiscal Effect <input type="checkbox"/> Increase Existing Revenues <input type="checkbox"/> Increase Costs <input type="checkbox"/> Decrease Costs <input type="checkbox"/> Indeterminate <input type="checkbox"/> Decrease Existing Revenues <input type="checkbox"/> Could Absorb Within Agency's Budget	
<b>8. The Rule Will Impact the Following (Check All That Apply)</b> <input type="checkbox"/> State's Economy <input type="checkbox"/> Specific Businesses/Sectors <input type="checkbox"/> Local Government Units <input type="checkbox"/> Public Utility Rate Payers <input type="checkbox"/> Small Businesses (if checked, complete Attachment A)	
<b>9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).</b> \$0	
<b>10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be \$10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)?</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
<b>11. Policy Problem Addressed by the Rule</b> Gabapentin is not a scheduled controlled substance. Gabapentin closely resembles pregabalin, a Schedule V controlled substance, in its chemical structure and pharmacological activity.  Gabapentin is a prescription medication approved by the Federal Food and Drug Administration for the treatment of neuropathic pain and epileptic disorders. In recent years however, Gabapentin has been increasingly encountered by law enforcement, documented in national crime lab reports, reported to poison control centers, and diverted for illicit use. The Researched Abuse, Diversion and Addictive – Related Surveillance (RADARS) indicates an increase in Gabapentin diversion. The Drug Abuse Warning Network (DAWN) indicates a rise of emergency department visit rates for Gabapentin.  The Controlled Substance Board and the Prescription Drug Monitoring Program (PDMP) staff has received requests by health care practitioners and law enforcement to have Gabapentin included in the PDMP. Prescribers have indicated it is beneficial to be aware of a patient having a prescription for Gabapentin prior to prescribing an opioid because when combined with opioids there is an increase risk of respiratory depression and opioid-related mortality increases significantly. Gabapentin is highly sought after for illicit use due to its potentiating opioids affect.  This rule designates Gabapentin as a drug having substantial potential for abuse. This designation would make Gabapentin a monitored drug in the PDMP.	
<b>12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.</b> The rule was posted on the department's website for 14 days to solicit economic impact comments from businesses, business sectors, associations representing business, local governmental units, and individuals. No comments were received.	
<b>13. Identify the Local Governmental Units that Participated in the Development of this EIA.</b>	

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None.

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14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)

No impact.

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15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule

The benefit of implementing the rule will be protect Wisconsin residents by including Gabapentin, which has a substantial potential for abuse, as a monitored drug in the prescription drug monitoring program.

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16. Long Range Implications of Implementing the Rule

The long range implication of implementing this rule will be to include Gabapentin as a monitored drug in the prescription drug monitoring program, which several of our surrounding states already do, and potentially reduce harm from the abuse of this substance.

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17. Compare With Approaches Being Used by Federal Government

There are no federal regulations regarding drugs monitored through state prescription drug monitoring programs. Gabapentin is not a federal controlled substance.

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18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

Illinois: Illinois has designated Gabapentin as a monitored drug in the prescription monitoring program.

Iowa: Iowa's prescription monitoring program designates reportable drugs as controlled substances administered or dispensed by a practitioner or opioid antagonist dispensed by a practitioner or administered by a first responder. There is no provision for designating drugs, such as Gabapentin, as a reportable drug. Iowa has not scheduled Gabapentin as a controlled substance.

Michigan: Michigan has scheduled Gabapentin as a Schedule V controlled substance. Michigan's prescription monitoring program requires all Schedule II-V controlled substances to be monitored.

Minnesota: For purposes of the prescription monitoring program, Minnesota includes Gabapentin in the definition of controlled substances and it is a monitored drug. Gabapentin is not scheduled as a controlled substance.

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19. Contact Name	20. Contact Phone Number
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**ADMINISTRATIVE RULES**  
**Fiscal Estimate & Economic Impact Analysis**

**ATTACHMENT A**

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1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

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2. Summary of the data sources used to measure the Rule's impact on Small Businesses

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3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?

- ☐ Less Stringent Compliance or Reporting Requirements  
☐ Less Stringent Schedules or Deadlines for Compliance or Reporting  
☐ Consolidation or Simplification of Reporting Requirements  
☐ Establishment of performance standards in lieu of Design or Operational Standards  
☐ Exemption of Small Businesses from some or all requirements  
☐ Other, describe:

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4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

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5. Describe the Rule's Enforcement Provisions

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6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

☐ Yes    ☐ No

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